

Applicants: Stan Gronthos *et al.*
Serial No.: 10/551,162
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REMARKS

Claims 68-81 are pending in the subject application. Applicants have not herein canceled, amended or added any claims.

Claims Rejections - 35 U.S.C. §102(b)

In the August 26, 2010 Office Action, the Examiner withdrew the previous rejection over Simmons *et al.* and U.S. Patent No. 7,122,178 in view of the recitation in claim 68 of "wherein at least 30% of the total cells of the population are positive for the marker 3G5." However, the Examiner stated that the rejection would be reinstated when the asserted new matter, identified hereinbelow, was removed from independent claim 68.

Claims Rejections - 35 U.S.C. §112, First Paragraph

In the August 26, 2010 Office Action, the Examiner rejected claims 68-81 under 35 U.S.C. §112, first paragraph, "as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Specifically, the Examiner asserted that the phrase "wherein at least 30% of the total cells of the population are positive for the marker 3G5" as recited in pending claim 68 constitutes "new matter."

Applicant's Response

Claim 68 recites "A population of cells enriched for 3G5 cells, wherein such 3G5 cells are mesenchymal precursor cells which comprise mesenchymal precursor cells capable of

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giving rise to colony forming unit-fibroblast (CFU-F), and wherein at least 30% of the total cells of the population are positive for the marker 3G5."

Applicants respectfully disagree with the Examiner's assertion that the phrase objected to is "new matter." The specification provides clear support for the claimed invention. Applicants direct the Examiner to page 16, lines 11-13, wherein it is stated:

"In the context of the present invention the term isolated cell may mean that perivascular MPCs comprise at least 30, 40, 50, 60, 70, 80, or 95% of total cells of the population in which they are present" (emphasis added).

In addition, the specification makes clear that MPCs can be isolated from, for example, perivascular or non-bone marrow tissue using the marker 3G5. Support for this can be found in the specification at page 1, lines 20-24 and also at page 10, lines 10-14, wherein it is stated:

"The present invention relates to mesenchmal precursor cells, in particular those that may be present in the perivascular compartment of vascularised tissue. Such mesenchymal cells may be identified by the presence of the 3G5 surface marker, and perhaps additionally or separately by other early developmental markers such as CD146 (MUC18), VCAM-1 and STRO-1" (emphasis added).

Accordingly, the disclosure at page 16, lines 11-13 and page 10, lines 10-14 of the specification provides clear and sufficient basis for the phrase in claim 68 "wherein at least 30% of the total cells of the population are positive for the marker 3G5."

Furthermore, in raising the new matter objection, the Examiner refers to the following three passages of the specification:

- (1) "Thus in bone marrow 3G5 positive MPCs constitute about 15% of MPC based on STR1^{bri} colony forming cells" (see page 13, lines 24-25);
- (2) "In the context of the present invention the term isolated cell may mean that perivascular MPCs comprise at least 30, 40, 50, 60, 70, 80, or 95% of total cells of the population in which they are present" (see page 16, lines 11-13); and
- (3) "Nevertheless, *in vitro* colony efficiency assays for different 3G5/CD146 FACS sorted sub fractions demonstrated that only a minor proportion (14%) of bone marrow clonogenic colonies expressed the 3G5 antigen at low levels (Figure 4B)" (see page 26, lines 10-12).

The above passages are not inconsistent with pending claim 68 because the reference to page 13, lines 24-25 and page 26, lines 10-12 relate to enrichment of MPCs from bone

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marrow, not from perivascular tissue. One skilled in the art reading the passage on page 13 in its entirety and in context would read:

"Thus in bone marrow 3G5 positive MPCs constitute about 15% of MPC based on STRO-1^{bri} colony forming cells, whereas in dental pulp that are found to constitute 65% and greater than 90% in fat and skin tissues" (emphasis added).

Thus, populations of cells enriched for 3G5 MPCs comprising 65% or greater of the total number of cells as 3G5 cells were obtained.

Accordingly, applicants maintain that the invention as claimed is clearly described and supported by the specification as filed and respectfully request that the Examiner reconsider and withdraw this ground of rejection.